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Avoiding Trade Secret Litigation In The Life Sciences

Law360, New York (August 06, 2012, 1:15 PM ET) -- Last September, a federal jury in Virginia awarded $919.9 million in damages to the DuPont Company for misappropriation of its trade secrets related to high-strength synthetic fibers used in Kevlar by South Korean company, Kolon. The jury found that Kolon intentionally had recruited and hired DuPont employees solely for purposes of obtaining information from them about Kevlar to use in the development of Kolon's competing product, Heracron.

That was the second largest trade secret award of 2011. In April 2011, a jury in Minnesota awarded St. Jude Medical Inc. $2.3 billion for the misappropriation of its trade secrets by a former employee who used them to start a competing medical device company in China.

As these unprecedented awards demonstrate, trade secret litigation is on the rise and the stakes are huge. Recent changes in research and business development strategies could put the prospect of trade secret litigation at the forefront of concerns facing biotechnology and pharmaceutical companies. Studies suggest that in at least 90 percent of recent trade secret cases, the alleged misappropriator was known to the trade secret owner. In as many as 40 percent of those cases, the alleged misappropriator was a business partner. As internal R&D decreases and more emphasis is placed on R&D outsourcing, collaborations, joint ventures, licensing and acquisitions, the risks associated with sharing valuable trade secret information likely will be magnified.

Currently, more than half of biopharmaceutical companies outsource at least some of their manufacturing to contract manufacturing organizations worldwide and that number is increasing. Such deals require the transfer of sensitive trade secret information. Likewise, in the context of strategic deals (licenses, collaborations, joint ventures and acquisitions), sensitive proprietary information nearly always must be shared during the diligence process.

Exercising appropriate control over such information exchanges always is sensitive, but the risks are especially heightened when, as is often the case, the proposed transaction does not consummate. Likewise, managing the exchange and control of information exchanged between collaborators over a period of years presents considerable challenges and risks, particularly if the collaboration ultimately is not successful for one or both parties.

A notable 2006 case, Eli Lilly and Co., v. Emisphere Technologies Inc., 408 F.Supp. 2d 668 (S.D. Ind. 2006), provides a good example of the risks involved with pharmaceutical development collaborations. Pharmaceutical giant Eli Lilly had collaborated with a small research company, Emisphere, on the development of new chemical carrier compounds. Over the course of their relationship, each party shared its valuable confidential information with the other pursuant to a research collaboration and option agreement and subsequent license agreement (which, it is worth noting, the court collectively described as "superb examples of sophisticated and complex draftsmanship"). Id. at 673.

The parties' relationship continued productively under those agreements for years, until negotiations of a more expansive collaboration agreement and license broke down over intellectual property concerns. Id. at 676, 678. In the face of those failed negotiations, yet while continuing to work with Emisphere, Eli Lilly simultaneously organized a new secret team engaged in what was unquestionably related research. Id. at 676-679. The team, led by two of the doctors involved in the Emisphere collaboration, then subsequently filed a patent application which incorporated information arguably learned during the parties' collaboration. Id.

In finding that Eli Lilly had breached its agreements with Emisphere, the court stated:

> Lilly and Emisphere entered into a close, collaborative research relationship that required trust and good faith on both sides. After several years of joint research, Lilly decided it really did not need Emisphere any further, so it decided to pursue a secret research strategy in breach of its contractual obligations to Emisphere. The parties in this case are both highly sophisticated and well-counseled businesses that have the right to try to exercise their full legal rights under the relevant contracts. Lilly has asserted theories to justify its actions under the contracts, but those theories are not supported by the evidence or the law. In the court's view, Lilly deliberately chose a course that was too aggressive, one that tried to sail too close to the wind. The result is this lawsuit, the termination of the contracts, and the loss of much of Lilly's investment.

Id. at 697.

Although the Eli Lilly case was a contract, not a trade secret case, it nonetheless serves as a cautionary tale for collaborators in the biotechnology and pharmaceutical industries regarding the necessity of taking proper steps to protect the secrecy of their trade secrets and position themselves to defend against allegations of trade secret misappropriation.

Internal Steps to Take Prior to Entering Collaboration Agreements

The most important first steps any company can take to protect its trade secrets (and, for that matter, to protect itself from allegations of misappropriation) are internal. Biotechnology and pharmaceutical companies are no exception. Starting with their own employees, companies should ensure that any employee who will have access to their confidential and trade secret information sign nondisclosure, intellectual property assignment, and/or noncompete agreements at the outset of his or her employment. These agreements should be specific, both in terms of scope and duration.

Employees should be required to document both their use of existing trade secrets and their development of any new trade secrets in internal notebooks. This step is especially important in order to preserve independent development defenses in any subsequent litigation involving accusations of misappropriation of another's trade secrets. The internal notebooks should be marked confidential and kept in locked cabinets and/or on password-protected computers, with access restricted to only a limited number of necessary employees.

Biotechnology and pharmaceutical companies are further advised to implement training and education programs regarding the company's confidentiality procedures and to mandate employees' involvement in these programs on an ongoing basis. They may also want to consider employing security personnel and/or purchasing security equipment to monitor any locations where trade secret information is kept. Finally, should any employees with access to confidential information end their employment, it is necessary to ensure that they are interviewed by human resources and reminded of their confidentiality obligations. It also is prudent to have IT review recent computer activity to ensure no trade secret files were removed or forwarded.

Unless and until these internal safeguards are in place, biotechnology and pharmaceutical companies should be extremely cautious about sharing their most valuable trade secrets with any potential collaborators.

Steps to Take in Negotiating Collaboration Agreements

Even before entering into any potential collaboration, biotechnology and pharmaceutical companies are advised to research their potential collaborator, with a keen eye to investigating and understanding the basis of any prior disputes or legal actions. In addition, it is essential that companies ask about the procedures their potential collaborator has in place to preserve the secrecy of any shared information. In preliminary meetings with potential collaborations, discussions should be limited to high-level and/or publicly available information only. Keeping detailed notes of these meetings is strongly recommended.

Once a framework for potential collaboration has been established, legal counsel should be involved promptly and, in any event, before any confidential information is exchanged. Rather than simply recycling a standard nondisclosure form, these companies should have their counsel draft an NDA that is narrowly tailored to specifically reflect the nature of the relationship, what confidential information is being shared, the scope of the intended disclosure and any subsequent use of it.

As the collaboration continues, legal counsel should be employed to negotiate any additional joint agreements as appropriate (e.g., letters of intent, joint development agreements, license agreements, etc.). Those agreements should similarly identify and define with specificity the trade secrets encompassed therein and to whom those trade secrets belong. In addition, they should specifically carve out any pre-existing IP rights that are not part of the agreement and address how the ownership of any newly developed and/or improved IP is to be determined. Well-drafted written agreements governing the parties' relationship are the best weapon in enforcing one's trade secrets against any would-be misappropriator.

Additional Considerations for Proceeding under Collaboration Agreements

While a well-drafted set of agreements will help collaborators enforce their trade secret rights in subsequent litigation, biotechnology and pharmaceutical companies should be especially cautious about overstepping the boundaries of those agreements, thereby making themselves the unwitting target of misappropriation accusations. The implementation of firewalls and/or clean rooms can help to ensure that those with knowledge of the collaborator's trade secrets are not tasked with developing substantially similar products. In such cases, legal counsel should be consulted and detailed records reflecting these arrangements made.

For example, one of the main factors contributing the court's finding that Eli Lilly had breached its agreements with Emisphere was the fact that (1) the firewall it erected had not been put in place until several months after the team had been created and Emisphere's confidential information shared, and (2) the Eli Lilly secret team included Eli Lilly employees who had worked on the collaborative project (one of which was the lead Lilly representative on the committee supervising the collaboration and who acknowledged that "the information he had gleaned from years of supervising the [collaboration] led him to have expectations about which carriers were likely to be most promising"). Eli Lilly, 408 F.Supp. 2d at 677, 682-685.

The court completely discredited testimony suggesting that the Eli Lilly team "relied only on published data and that none of the information from the Emisphere collaboration was useful," and found that Eli Lilly had, at minimum garnered a head start, when it used information developed during the parties' collaboration. Id. at 682-683.

Conclusion

Trade secret litigation is on the rise and biotechnology and pharmaceutical collaborators are particularly at risk. Instituting internal procedures to maintain the secrecy of trade secrets, diligently researching potential collaborators and engaging legal counsel to draft narrow and specific agreements to govern any such relationships, and implementing firewalls between employees working on the collaboration and those working on new developments are essential steps these companies must take to minimize their risks.

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